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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/702,498      | 10/31/2000  | Tsuyoshi Tokusumi    | 50026/025001        | 9833             |

7590 12/04/2001

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EXAMINER

FOLEY, SHANON A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1648

DATE MAILED: 12/04/2001

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/702,498

Applicant(s)

TOKUSUMI ET AL.

Examiner

Shanon A. Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 7.                      6) ☐ Other:

## **DETAILED ACTION**

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on May 18, 2000. It is noted, however, that applicant has not filed a certified copy with the instant application as required by 35 U.S.C. 119(b).

### ***Specification***

The specification is objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID NOs to all mentions of specific sequences of nucleic acids more than 10 nucleotides in length, for example on page 14, line 31. See 37 CFR § 1.821(a) and MPEP § 2422.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to DNA that has not been isolated and cannot be distinguished from a natural product. This rejection can be obviated if applicant amends the claims to recite "isolated" before "DNA".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are unclear because claims 1 and 5 state that the foreign gene is located "downstream" of the genes encoding viral proteins. In other words, the foreign gene is located at the at the 5' end of the paramyxovirus genome after the L gene. However, claims 2 and 6 state that the gene is located between certain genes encoding viral proteins, not at the end. This constitutes a discrepancy within the claims as to where the foreign gene is located.

Claims 2 and 6 are vague and indefinite because (f) states that the foreign gene is inserted between the 6th gene encoding a viral protein and the 3' end of the RNA. Since the viral genome is 3' to 5', see page 1314 of Fields et al. (Virology, 3rd edition. Vol. 1. Philadelphia. Lippencott Williams and Wilkins Publishers. 1996), it is presumed that applicant intended for the gene to be inserted between the 6<sup>th</sup> gene and the 5' end of the genomic RNA.

Claims 3 and 7 are vague and indefinite for reciting the phrase "in their order". Are the recited genes in genomic order respectively? It is also noted that not all paramyxoviruses share this gene order, such as RSV and mumps, see the previous citation of Fields et al.

Claim 4 is indefinite for reciting "or their complementary strands". Whose strands are being referred to? Also, claim 1 describes only one paramyxovirus variant with a foreign gene located at the end of the genomic RNA. Therefore, the paramyxovirus of claim 1 would only have one complementary strand.

Claim 5 is vague and indefinite for reciting "its complementary strand". It cannot be discerned which nucleic acid is complemented, the DNA or the genomic RNA.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Tokusumi et al. (The Third Annual Meeting of the American Society of Gene Therapy, Program 890 (May 31-June 4, 2000)).

The claims are drawn to a replicable paramyxovirus encoding a foreign gene downstream of the viral proteins and located between viral proteins.

Tokusumi et al. teaches a Sendai virus (SeV) vector expressing a foreign reporter gene, SEAP, between each of the five foreign genes to monitor expression, see the abstract in the IDS of paper no. 6.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kato et al. (Journal of Virology. 1999; 73 (11): 9237-9246).

Kato et al. teaches a recombinant SeV that expresses a luciferase gene between the N and the P gene, see the abstract and figure 1.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Conzelmann et al. (EP 0 702 085 A1).

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Conzelmann et al. teaches a replicating paramyxovirus comprising an insertion in the open reading frames of the pseudogene and M regions, see claims 1, 3-5, 8, and 9.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Conzelmann et al. (US 6,033,886)

Conzelmann et al. a replicating paramyxovirus comprising an insertion in the open reading frames of the pseudogene and M regions, see claims 1-4, 8, and 9.

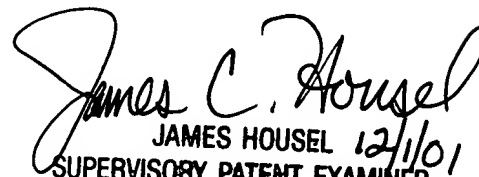
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF  
November 27, 2001

  
JAMES HOUSEL 12/1/01  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600